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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
HAQ, SHAFIQUL	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 12/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/525,626	NISHII ET AL.	
	Examiner	Art Unit	
	Shafiqul Haq	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 October 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *2/24/05,7/8/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-11 are pending.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 5-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

4. With respect to claim 5, it is not clear what is meant by "competitive antigen" in the context of a "kit". An "antigen" is typically used to prepare an antibody and as understood from the specification of present application, compound of formula (1) is not used for production of anti-dioxin antibodies. If the "competitive antigen" is different from the compound of formula (1), then it is unclear what antigen(s) or compound(s)/conjugate are encompassed by the term "competitive antigen"?

5. Claims 6-9 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: the steps to specifically describe an "immunoassay of (for?) dioxins" as recited in preamble of claims 6 and 8. An appropriate sequence of method steps would include a step in which specific binding between the corresponding members of a specific binding pair occurs, a step for the detection of this binding by the use of an appropriate label (tracer?) and a step for the correlation of the detection of binding with the presence/amount of

dioxin analyte in the sample. Alternatively, Jepson language may be appropriate (in an immunoassay for the detection of dioxins.....wherein the improvement comprises..."). The claims provide for the use of compound of formula (1) in an immunoassay, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

6. Claims 6 and 8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 7 and 8 provide for an immunoassay method using the compound of claim 1, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.
7. With respect to claim 10, it is unclear how the antigen is detected in the immunoassay method i.e it is not clear whether anti-dioxin antibody is labeled with a detectable label or is detected by secondary labeled antibody. An appropriate method step(s) for the detection of this binding by the use of an appropriate label (tracer) is required to clearly define the method steps.
8. Claim 10 recites the phrase "An immunoassay method for dioxins". It is not clear from claim language whether the "immunoassay method" is intended for quantitative

determination or detection of dioxins in a sample. i.e. the intended use of the immunoassay method is not clear.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by Hatzidakis et al (Anal. Chem, 2002).

Hatzidakis et al describe conjugates of 2,4-dichlorophenoxyacetic acid (2,4 D) and 2,4,5 trichlorophenoxyacetic acid (2,4,5 T) with amino acids and BSA (see abstract and compounds of Fig. 1) which anticipate the compound of formula (1) of instant claims 1-3.

With respect to claims 2-3, the claims are directed to compound of formula (1) and the recitation "immunoassay standard for dioxin" and "immunoassay kit for dioxins" in claims 2 and 3 have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Applicant is reminded that a recitation of the intended use of the claimed invention, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Therefore, the reference is deemed to anticipate the cited claims.

11. Claims 1-3 are rejected under 35 U.S.C. 102(a) as being anticipated by each of the unexamined Japanese patent publications 2002-128731, 2002-131316 or 2002-155023.

Each of the unexamined patent publications disclose compound 1 (see translated abstract) that anticipates compound of formula (1) of instant application when the referenced compound is conjugated with a peptide or proteins. Note that succinimidyl ester of the compound 1 of the unexamined patent publications, when conjugated with protein (e.g. BSA) would produce a peptide/protein conjugated to the compound through an amide bond and therefore, anticipates compound of formula (1) of instant application. The publications also disclose using the compound as standard in immunoassay (see figs. 1, 2 and 3).

Therefore, the references are deemed to anticipate the cited claims.

12. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Feung et al. (J. Arg. Food Chem. 1973).

Feung et al describe 2,4-dichlorophenoxyacetic acid (2,4 D) conjugate with amino acids (See Experimental section of page 632 and Fig.2 of page 633) which anticipate the compound of formula (1) of instant claims 1-3.

With respect to claims 2-3, the claims are directed to compound of formula (1) and the recitation "immunoassay standard for dioxin" and "immunoassay kit for dioxins" in claims 2 and 3 have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Applicant is reminded that a recitation of the intended use of the claimed invention, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Therefore, the reference is deemed to anticipate the cited claims.

13. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Carlson et al. (US 5,538,852).

Carlson et al describe chlorinated phenoxy conjugate with BSA and KSA (Formula I of front page, column 4; compound 15 of Fig.4 and claim 14 and example 5) which anticipate the compound of formula (1) of instant claims 1-3. Note that Formula 1 (e.g.compound 15 of Fig.4) of reference compound when conjugated with KLH or BSA through carbodiimide mediated carboxyl activation (column 15, lines 55-57) reads on the compound of formula (1) of instant compound conjugated with peptide.

With respect to claims 2-3, the claims are directed to compound of formula (1) and the recitation "immunoassay standard for dioxin" and "immunoassay kit for dioxins" in claims 2 and 3 have not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone.

Applicant is reminded that a recitation of the intended use of the claimed invention, must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See In re Casey, 152 USPQ 235 (CCPA 1967) and In re Otto, 136 USPQ 458, 459 (CCPA 1963).

Therefore, the reference is deemed to anticipate the cited claims.

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 6, 7 and 9-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 2003/0054424 A1) in view of Carlson et al (US 5,538,852) and Hatzidakis et al (US Anal. Chem. 2002).

Allen et al. disclose immunoassay method for quantitative determination of polychlorinated biphenyl compounds (dioxins). The method comprises reacting sample with anti-dioxin antibody, measuring the antibody bound to analyte (dioxins) in the sample and relating the binding label of antibody with binding label of antibody with control composition of known concentration (see abstract and claim 1 of page 11). The control/standard used in this immunoassay comprise polychlorinated biphenyl compounds of known concentration (see claim 1).

Allen et al. disclose polychlorinated biphenyl compounds as control/standard as described above. Allen et al., however, fail to disclose polychlorinated phenoxy conjugates as control/standard in the immunoassay method.

Carlson et al. disclose competitive immunoassay methods for determining the amount of polychlorinated biphenyls (dioxins) in which chlorinated phenoxy (Formula I of front page, column 4; compound 15 of Fig.4 and claim 14) conjugates with BSA

or KHL (see example 5) are used as competitors/control in the immunoassay method (column 11, lines 40-45). Carson et al. disclose that different immunoassay such as enzyme immunoassay, radioactive immunoassay etc. can be used with the competitor (column 11, lines 40-46 and column 6, lines 40-48).

Carson et al. further disclose that sensitivity of the immunoassay is expected to enhance by selecting a competitor that does not substantially duplicate the hapten (column 9, lines 35-47). Polychlorinated phenoxy conjugates have a lower affinity for anti-PCBs antibodies than the antibodies have to the polychlorinated biphenyls and therefore, polychlorinated phenoxy conjugates as competitor/control are preferred over biphenyl conjugate which results in improved detection sensitivity (column 9, lines 36-47; column 3, lines 15-54).

Hatzidakis et al also disclose Polychlorinated phenoxy conjugates (2,4D and 2,4,5T) as standard in immunoassay method (page 2517, left column, lines 6-14; see 2.4D assay in page 2518 and Fig.2).

Therefore, given the above fact that use of polychlorinated phenoxy conjugates is known in the art and is useful as a competitor/standard in immunoassay to improve detection sensitivity (Carson et al. and Hatzidakis et al), it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to incorporate polychlorinated phenoxy conjugates of Carson et al or Hatzidakis et al in the method of Allen et al as standard or competitor, with the expectation of improving the detection sensitivity of polychlorinated biphenyls (dioxins).

16. Claim 8 and 9 are obvious over the prior art as applied in the immediately preceding paragraph 15 and further in view of the admitted prior art as set forth at page 5, lines 7-17 of the specification.

Preceding paragraph 15 disclose immunoassay method but do not disclose calculating TEQ.

Admitted prior art disclose that calculation of TEQ value in immunoassay detection of dioxins is common and know in the art for dioxin determination (Specification, page 5, lines 7-17).

Therefore, it would have been prima facie obvious to one of ordinary skill in the art at the time of the instant invention to include calculation of TEQ value in the method of Allen for determining amount of dioxins in a sample.

17. Claims 3-5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Allen et al. (US 2003/0054424 A1), Carlson et al (US 5,538,852) and Hatzidakis et al (US Anal. Chem. 2002) as applied in the preceding paragraph 15 and further in view of Friedman et al. (5,834,222).

As disclosed in paragraph 12, prior arts disclose immunoassay method for dioxins but do not disclose immunoassay components compiling in a kit format.

Friedman et al. in an immunoassay method for determination of polychlorinated biphenyls (dioxins) disclose kit comprising anti-PCBs antibody, a standard solution and a hapten conjugate.

Since immunoassy components in kit format is know and common in the art for dioxins detection (Friedman et al.), it would have been prima facie obvious to one of

ordinary skill in the art at the time of the instant invention to compile components of immunoassay in kit format for ease and convenience in immunoassay performance.

Double Patenting

18. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement. Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

19. Claims 1-5 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 3-6 of copending Application No. 10/687,684 (US 2004/0191846A1). Although, conflicting claims are not identical, they are not patentably distinct from each other because claims 3-6 of copending application are drawn to a compound of formula (II) that reads on the compound of formula (1) of present application when R^2, R^4 = chlorine and R^1, R^3 = hydrogen and both the kits comprise the above compound. The only difference is that the kit of present claims further comprise an anti-dioxin antibody known in the

art (see specification, page 21, lines 14-22) but whether or not to include the anti-dioxin antibody in the kit is a matter of choice for ease and convenience and therefore, the kit claims are obvious over the claims of copending application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

20. No claims are allowed.

21. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shafiqul Haq whose telephone number is 571-272-6103. The examiner can normally be reached on 7:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long V. Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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12/09/05